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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,732	08/08/2001	Paola Vianello	328/US	3934

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EXAMINER	
FORD, JOHN M	
ART UNIT	PAPER NUMBER
1624	4

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/924,732	Viarello et al
Examiner	**Group Art Unit**
Jim Ford	162X

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on April 15, 2002.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above claim(s) 9-10 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Exhibit A Comm. Memo.

Office Action Summary

Applicant's response of April 15, 2002, is noted.

The claims in the application are claims 1—18.

Claim 1 is rejected under 35 USC 112, 1st and 2nd paragraphs.

(A) Line 3 refers to a "prodrug". No one knows what that would be. It is a complete "other" invention to determine what compound, fed to a mammal would produce the instant compounds. It is suggested the word "prodrug" be removed from the claims, as unsupportable.

(B) Note "aryl" in the R_2 definition, line 2. What do applicants intend by aryl? Judge Smith noted in the footnotes of In re Sus , 134 USPQ 301, that there are, in fact, multiple, different, definitions of aryl. Therefore, applicants need to indicate in the claims, what they intend b y aryl. Aryl in R_1 is, likewise, rejected.

(C) Likewise, in R^2 at the top of page 69, applicants have a heteroaryl expression that is the type held unclear in In re Wiggins, 179 USPQ 421. Applicants need to provide a clear list of specific rings they wish to claim.

Claim 2 is rejected under 35 USC 112, 1st and 2nd paragraphs. Note "aralkyl" in R_2. What do applicants intend? Note the rejection of aryl in claim 1.

The specification serves various purpose, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out

of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

Applicants need to indicate, in the claims, what they intend by aryl.

What is the purpose of the proviso statement at the end of claim 2?

What is the purpose of the proviso statement at the end of the claim. Is prior art being written around? In re Nomiya et al, 184 USPQ 607, provides the next adjacent compounds to those removed by exception may be rejected as structurally obvious under 35 USC 103, from those removed.

Applicants cannot successfully argue, unity of invention while removing certain compounds. The next adjacent compound to those removed, by exception would be structurally obvious from those removed. In re Nomiya et al, 184 USPQ 607, indicates a rejection over the compounds removed is acceptable, whether we know the citation of the compounds or not. We reject by means of the compound, not the citation of the compound.

Claim 3 is rejected under 35 USC 112m 1st and 2nd paragraph, as a result of the use of "aralkyl" in the R_2 definition. Note the rejection of aryl in claims 1 and 2.

Claim 4 is rejected as failing to comply with 37 CFR 1.141. The Rule provides for a reasonable number of species. Claim 4 is not a reasonable number of species. In 1964, when I started in the USPTO, Rule 141 provided for 5 species in such a dependent claim. Then the Rule was changed to a reasonable number. Claim 4 is not a reasonable number. NO determination of patentability can be made in claim 4 in

the limited time provided to examine the entire application. No generic concept is provided by the claim. Each species has to be written out, separately, into a structural representation to classify each species. Applicants paid $18.00 for claim 4. Each species has to be searched separately to determine patentability. No time is provided to do that. It costs $35.00 to search each species, separately, in CAS-on-line. The USPTO is losing money on a claim of the type noted in claim 4. The word "different" been added to Rule 141 to provide that each ultimate species be in a separate claim. Note Exhibit A, a memo on this type of claim from Commissioner Wahl. In re Fressola, 22 USPQ (2nd) 1828 provide that the Rules have the force of Law.

Claim 5 is rejected for the reasons claim 1 was rejected.

Claim 6 is rejected for the reasons claim 2 was rejected.

Claim 7 is rejected for the reasons claim 3 was rejected.

Claim 8 is rejected as a result of the use of the word "prodrug". See the rejection of claim 1.

Claim 8 is rejected as an instance of more than a reasonable species, for the reasons noted in the rejection of claim 4.

Claim 9 is not acceptable under 35 U.S.C. 112. 1st paragraph, as the treatment of a condition mediated by α_2 β_3 integrin is not a specific, real world utility.

That is a laboratory test, not a specific, singular, utility.

The treatment noted in claim 9 cannot be acceptable as one specific utility. See claims 13—16. The recent utility guidelines set by USPTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which requires that

utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is whether the invention has been brought to such perfection as to be capable of practical employment. This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

MPEP 806.05(h), as does 37 CFR 1.475 and PCT Rule 13.2, provides for one method of use to be examined with the elected compounds. A broad disclosure of Utility, as in the cited claim 9, cannot be deemed in compliance with 35 USC 112, first paragraph.

The USPTO has amended the guidelines to require a "specific utility." The Court focused on the facet that the applicant failed to identify a "Specific utility" in Brenner v. Manson.

This requirement of one specific utility is also in compliance with 37 CFR 1.475; the Unity of Invention Practice in International Applications and National Phase Applications under 35 USC 371, and PCT Rule 13.2.

Therefore, applicants should limit the method claims to a sole "specific utility", that complies with Brenner vs. Manson as a real specific utility that relates to the real world of Commerce.

Applicants need to pick one believable utility for the claims.

Examples of generalized and vague assertions of utility which do not meet the disclosure requirement of 35 USC 112 are: statement that a product is a pharmaceutical", "therapeutic agent", or has "biological utility", or is "an intermediate to

make a drug", citing, respectively, In re Diehrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Lorenz et al. (CCPA 1962) 305 F2d 875, 134 USPQ 312 and Ex parte Brokman et al. (POBA 1959) 127 USPQ 57 ; In re Kirk et al. (CCPA 1967) 153 USPQ 48 ; and In re Joly et al. (CCPA 1967) 376 F2d 906, 153 USPQ 45.

The "how to use " requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compounds, if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Driedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138. Thus, where the claimed compounds are not structurally similar to known compounds having the same activity, and their pharmaceutical properties could not be predicted their chemical structure, a disclosure that they posses a particular activity against a pathological organism (antitubercular activity) may not suffice as a description of how to use as required by 35 USC 112. In re Moureu et al. (CCPa 1965) 345 F2d 595, 145 USPQ 452.

Statements of utility, which relate to or imply the treatment of a disease are subject to closer scrutiny. Ex parte Moore et al. (POBA 1960) 128 USPQ 8. Thus when the disclosed utility is the production of a physiological response, e.g. antidepressant effect, the dosage effective to achieve this response in host, whether human or animal, must be disclosed. In re Garner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

The fact that structurally unrelated prior art compounds may have been used to protect the liver from the effects of hepatitis does not render obvious to one skilled in the art how to use a novel compound disclosed to "assist the liver Function in hepatic

disturbances and can, therefore, be used as medicament in humans and veterinary medicine". In re Schmidt et al. (CCPA 1967) 377 F2d 639, 153 USPQ 640.

A specification, which discloses only one mode of administration of medicinal for the purpose of effecting a modification in a body function, does not provide support for a claim not limited to that specific mode. Ex parte Proctor (POBA 1966) 158 USPQ 677.

A method claim which designates amount of an ingredient of a claimed method as "an effective amount" is too broad and indefinite if it does not designate the intended effect; Ex parte Dobson et al. (POBA 1969) 165 USPQ 29. In re Fedriken, 102 USPQ 35, (CCPA 1954) A cancer or a tumor, or a solid tumor is not specific to one disease.

Issentstead v. Watson, (DCDC 1957) F Supp. 7, 115 USPQ 408 and Schindler v. Comr of Pats. (DCDC 1967) 157 F Supp 630, 155 USPQ 838. Note where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev v. Brenner, Ferguson, (POBA 1957) 117 USPQ 229.

Where utility is based on the alleged enhancement of activity of know medicinals. The CCPA up held the Examiner's requirement that the applicant submit evidence, which substantiated the allegation unless one skilled in the art would accept them as obviously valid and correct. In re Novak et al., (CCPA 1962) 306 F2d 924, 134 USPQ 335.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof when such use is a medical nature for the treatment of a serious disease, such as cancer. Ex parte Moore et al. , (POBA 1960) 128 USPQ 8 ; In re Citron, (CCPA 1964) 325 F2d 248, 139 USPQ 516 ; In re Hartop et al. , (CCPA 1962) 311 F2d. 135 USPQ 419.

The Supreme Court declined to expresses a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. V. Manson, (USC 1966) 383 US 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing reasoning the patent system is related to the world of commerce, rather than the realm of philosophy ibid., 148 USPQ at 696.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data the acceptance of the drug employed by the Food and Drug Administration and by American Medical Association specification. Ex parte Timmis, (POBA 1959) 123 USPW 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven cancer, was held insufficient to establish the utility of claims directed to a method of treating seven cancers. In re Butting, (CCPA 1969) 418 F2d, 163 USPQ 689.

MPEP 806.05(h) indicates that claims 9—18 may be held withdrawn altogether, if they are not limited to one provable utility.

The claims themselves act as evidence claims to the allegation that the compounds may be used more than one purpose. One specific, provable, utility is all that can be examined here with the compounds.

JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624

JMFord
June 1, 2002
Art Unit 1624